

AFTER FINAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Lixiao WANG, et al.
SERIAL NO. : 10/694,050
FILED : October 28, 2003
FOR : METHOD AND APPARATUS FOR SELECTIVE ABLATION
OF COATINGS FROM MEDICAL DEVICES
GROUP ART UNIT : 1725
EXAMINER : Samuel M. Heinrich

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

SIR:

The claims in the above-referenced application were finally rejected in the final Office Action mailed June 12, 2007 ("Final OA"). Applicants respectfully submit this Pre-appeal Brief Request for Review. A Notice of Appeal is concurrently submitted herewith. The Commissioner is hereby authorized to charge any fees associated with this filing to Kenyon & Kenyon LLP deposit account no. 11-0600.

REMARKS

Claims 1-8, 10-26 are currently pending in this application. Claims 1-8, 10-12 and 23-26 have been withdrawn from consideration by the Examiner. Accordingly, claims 13-22 are the subject of this Pre-appeal Brief Request for Review.

The Final OA rejected claims 13-22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,107,004 to Donadio, III ("Donadio") in view of U.S. Patent No. 5,421,955 to Lau et al. ("Lau"), and in view of U.S. Patent No. 5,267,381 to Wright et al ("Wright"). Applicants respectfully submit that the claims are patentable over the cited references for several reasons, and that there are clear errors in the rejection.

Independent claim 13 recites the structural limitations of a pattern recognition system “adapted to identify the positioning of at least one strut of a medical device relative to the laser, determine whether the strut is in a desired position relative to the laser, and provide output to correct positioning of the strut relative to the laser”—none of which is disclosed or suggested by any of the three references, alone or in combination. In addition, none of the references discloses or suggests the limitation of a laser “adapted to ablate ... coating ... based on output from the pattern recognition system.” Thus, for at least these reasons, the provisionally elected claims are patentably distinct over the cited references.

A. The References Do Not Disclose Or Suggest A Pattern Recognition System “Adapted To Identify The Positioning ... Relative To The Laser” And “Determine Whether [The Device] Is In A Desired Position Relative To The Laser.”

Neither Donadio nor Lau discloses or suggests a pattern recognition system; thus, these two references do not supply the above missing limitations.¹ Wright also fails to disclose or suggest a pattern recognition system as claimed. The Final OA points to only col. 7:42-45 of Wright as regarding a pattern recognition system. *See* Final OA, p. 2. However, the referenced passage in Wright regards a pattern recognition of the “ability to determine the type of defect, such as a step or nick, on the face 30 of tube 18,” (*see* Wright, col. 7:42-45), by sensing “the height differential on the face 30 of tube 18.” *See* Wright, col. 7:34-35. In doing so, the device in Wright “compare[s] the output ... with the preset acceptable limits programmed into processing means 94 ... to determine if tube 18 is acceptable as a tube with a good tube face.” *See* Wright, col. 7:47-51; 8:44-53. In other words, the dimensional tolerance system of Wright uses a pattern recognition system to compare the surface defects of the tube face relative to a “preset” surface pattern to check for dimensional tolerances (*e.g.*, surface waviness such as “nicks” or “steps” on the face). Wright, by comparing output data of tube face height dimensions against dimensions of a “preset” model pattern of a “good tube face” to determine dimensional compliance (Wright, col. 7:47-51; 8:44-53), does not disclose or suggest at least the limitations of a pattern recognition system “adapted to identify the positioning of at least one strut of a medical device relative to the laser” and “determine whether the strut is in a desired position relative to the laser” for corrective laser ablation.

¹ Donadio generally regards using electrodes to cut slots in a stent by electrostatic discharge machining. *See* Donadio, Abstract. Lau generally regards removal of an etchant-resistive coating mask to expose the substrate surfaces for removal of underlying material by a chemical etch to form a stent. *See* Lau, col. 3:17-27. Neither mentions, discloses, describes or suggests a pattern recognition system.

B. The Cited References Do Not Disclose Or Suggest A Pattern Recognition System Adapted To “Provide Output To Correct Positioning ... Relative To The Laser” Or A Laser “Adapted To Ablate ... Coating ... Based On Output.”

Moreover, none of the cited references discloses or suggests at least the limitation of a pattern recognition system adapted to “provide output to correct positioning of the strut relative to the laser.” Again, neither Donadio nor Lau discloses or suggests a pattern recognition system. Wright also does not disclose the pattern recognition as claimed because it does not provide information to assist in corrective re-positioning of devices that have been mis-positioned, let alone provide re-positioning output data relative to the laser to ensure accurate ablation by the laser. Wright does not provide output for corrections to the controllers to alter stent positioning relative to a laser. Rather, in Wright “[i]f the analysis determines that a defect exists on the face 30 for tube 18, then tube 18 will have to be reworked. ... To rework tube 18, tube 18 may remain at the same location. As previously described, the cutting mechanism may cut and finish the face” followed by an inspection. *See* Wright, col. 8:53-60. Thus, the device in Wright merely re-cuts the face without re-positioning the tube, and compares the re-cut face against the preset model pattern again. Wright does not provide output to “correct positioning of the strut,” as claimed. Furthermore, Wright does not disclose or suggest adapting a laser to use any output or corrective information to ablate a coating, as claimed.

C. The Claim Limitations Are Due Patentable Weight.

The Final OA states that Applicants assertion that the “claimed system is adapted to identify the positioning of a work piece ... is not convincing ... [since] [t]he process of use does not impart patentability to the apparatus.” *See* Final OA, p. 3. Applicants respectfully assert that this rejection cannot be maintained because the claim language recognizes and emphasizes the difference between the claimed invention and the cited references, and deserves patentable weight as non-functional language for the reasons stated below.

First, Applicants’ claim limitations specifically recite non-functional “structural attributes.” Claim 13 recites a pattern recognition system “adapted to identify the positioning of at least one strut of a medical device relative to the laser” The CCPA “Court held that limitations such as ‘members adapted to be positioned’ ... serve to precisely define present structural attributes of interrelated component parts of the claimed assembly.” *See* MPEP §2173.05(g); *see also Pac Tec, Inc. v. Amerace Corp.*, 903 F.2d 796 (Fed. Cir. 1990) (language in “adapted to” clauses cannot be disregarded). Thus, the language in the claims is not functional “process of use” language and provides structural limitations.

Second, the language in the claims should be accorded patentable weight because Applicants' recitation of a pattern recognition system so adapted limits the claims to specific structure (*i.e.*, a pattern recognition system specifically adapted to determine positioning relative to a laser, and provide output to correct positioning of the device relative to a laser) and, thus, is non-functional language. *See* MPEP §2173.05(g). Language that limits the structure of the claimed invention should be treated as a claim limitation with due patentable weight accorded to it. *See Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

Third, if the recited purpose or intended use recognizes a difference between the claimed invention and the prior art, the recitation serves to limit the claim and deserves patentable weight. *See, e.g., In re Otto*, 312 F.2d 937, 938, 136 U.S.P.Q. 458, 459 (C.C.P.A. 1963). Here, Applicants' recitation of a pattern recognition system that is adapted to identify and determine positioning of a device relative to a laser, and a laser adapted to ablate coating based on output from the pattern recognition system, recognizes the differences with the cited references, and thus should be treated as a claim limitation with patentable weight. *Id.*, at 938.

D. There Is No Support To Make The Suggested Modification.

The Final Office Action stated that “[i]n response to applicant’s arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.” *See* Final OA, p. 3. To the contrary, Applicants previously argued in its Response to December 5, 2006, Office Action that the asserted combination failed to disclose or suggest at least one limitation of claim 13.² None of the references, alone or in combination, discloses or suggests at least the limitations discussed above for all the reasons mentioned above.

Regardless, there can be no support to modify the references in the manner suggested for several reasons. First, there is no support for modifying the primary reference of Donadio, or the secondary reference of Lau, with Wright to find the claimed pattern recognition system “adapted to identify the positioning of at least one strut of a medical device relative to the laser” because such a proposed modification would render the primary reference of Donadio and the Lau reference “unsatisfactory for its intended purpose.” *See* MPEP 2143.01 (V) (“If the proposed modification would render the prior art invention being modified unsatisfactory for its intended

² Applicants stated “that none of the references, alone or in combination, discloses or suggests at least the above limitations” of “a pattern recognition system adapted to identify the positioning of at least one strut of a medical device relative to the laser, determine whether the strut is in a desired position relative to the laser, and provide output to correct positioning of the strut relative to the laser.” *See* Applicants’ Response to December 5, 2006, Office Action, p. 8.

purpose, then there is no suggestion or motivation to make the proposed modification.”). Both Donadio and Lau describe processes conducted on solid tubes—thus, there is no strut to be identified. Both Donadio and Lau relate to creating stents by cutting strut patterns from solid tubes.³ This is in contrast to the claimed invention, in which the ablation operation is conducted on a patterned stent with struts, as opposed to a solid tube. In the claimed process, there are struts to recognize. In Donadio and Lau, there is only a solid tube, and thus no struts to recognize until after the cutting operation is completed. Thus, there is no reason to modify the strut-forming processes described in Donadio and Lau, with a pattern recognition system that identifies positioning of already formed struts. Such a suggested modification to Donadio is unhelpful and unnecessary for its intended purpose of forming struts.

Second, there can be no support to modify the references where the “suggested combination would require a ... change in the basic principle under which the primary reference’s construction was designed to operate.” MPEP 2143.01 (VI). Modifying the pattern recognition system of Wright to identify the device positioning relative to a laser instead of a preset face pattern changes the operation of Wright. In addition, the system in Wright does not provide output for corrective re-positioning, as discussed above.

Third, there is no reason or support to make the suggested combination because Wright teaches away from doing so. As discussed above, Wright does not provide output for corrections to alter stent positioning. Rather, in reworking the tube in Wright, the tube remains at the same location. Wright, col. 8:53-60. Thus, Wright teaches away from changing the position of the device based on corrective output from the pattern recognition system.

Respectfully submitted,

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/ Ronald L. Sigworth /
Ronald L. Sigworth
Reg. No. 53,592

KENYON & KENYON LLP
1500 K Street, N.W.
Washington, D.C. 20005
202-220-4200 (phone)
202-220-4201 (facsimile)

³ See, e.g., Donadio, Abstract (“creating a pattern of slots or apertures in a flexible tubular member, by processes including ... ablation and laser cutting. These slots may be cut completely or partially through the wall of the ... tubular member.”); and Lau, Abstract (“The stents are made by coating a length of tubing with an etchant-resistant material and then selectively removing portions of the coating to form a pattern for the stent on the tubing to expose the portions of the tubing to be removed. ... After the patterning of the tubing, the stent is formed by removing exposed portions of the tubing by an etching process.”)